Fox, Yvette (DOH)

To: Heart Surgery; Heart Surgery Workgroup; Heart Surgery Workgroup CC:; (FSL-ruledevelopment@listserv.wa.gov)

Subject: Heart Surgery Rules - First Preliminary Draft

Attachments: First Preliminary Draft.doc; Sample Need forecasting method.doc

Attached is a very preliminary first draft, or straw man, to use as we begin discussion of the non-emergent adult percutaneous interventional cardiology rules. This 1st document includes topic areas to be considered for including in the final rules. Also attached is sample need methodology language to get us started as we discuss the numeric need forecasting methodology.

Please come to the November 15, 2007 meeting, prepared with suggested language for these topics areas. If there any additional topic areas you would like to see included in the final rules please come prepared with suggested language for them as well.

I will send you actual meeting times and locations for our meeting on November 15 and future meetings in the next few days.


First Preliminary Draft.doc (8...


Sample Need orecasting method..

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The Department of Health works to protect and improve the health of people in Washington State.

WAC 246-310-262 NON-EMERGENT ADULT PERCUTANEOUS INTERVENTIONAL CARDIOLOGY

Percutaneous coronary interventions (PCI) are tertiary services as listed in WAC 246-310-020. To be granted a certificate of need, a non-emergent adult percutaneous interventional coronary program must meet the standards in this section in addition to applicable review criteria in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240.

Definitions

Percutaneous coronary interventions (PCI) mean invasive but non-surgical mechanical procedures and devices that are use by cardiologists for the revascularization of obstructed coronary arteries. These interventions include, but are not limited to:

- Bare and drug-eluting stent implantation
- Percutaneous transluminal coronary angioplasty (PTCA)
- Cutting balloon atherectomy
- Rotational atherectomy
- Directional atherectomy
- Excimer laser angioplasty
- Extractional thrombectomy.

Non-Emergent means: ??????

Primary PCIs means: ??????

Planning area means: each individual geographic area designated by the department for which non-emergent adult percutaneous interventional coronary program need projections are calculated. For purposes of non-emergent PCI projects, planning area and service area have the same meaning.

Planning Area Boundaries means: ?????

Capital expenditures, as defined by Generally Accepted Accounting Principles (GAAP), are expenditures made to acquire tangible long-lived assets. Long-lived assets represent property and equipment used in a company's operations that have an estimated useful life greater than one year. Acquired long-lived assets are recorded at acquisition cost and include all costs incurred necessary to bring the asset to working order. The definition of a capital expenditure includes the following types of expenditures or acquisitions:

- A force account expenditure or acquisition (i.e., an expenditure for a construction project undertaken by a facility as its own contractor).
- The costs of any site planning services (architect or other site planning consultant) including but not limited to

studies, surveys, designs, plans, working drawings, specifications, and other activities (including applicant staff payroll and employee benefit costs, consulting and other services which, under GAAP or Financial Accounting Standards Board (FASB) may be chargeable as an operating or nonoperating expense).

- Capital expenditure or acquisition under an operating or financing lease or comparable arrangement, or through donation, which would have required certificate of need review if the capital expenditure or acquisition had been made by purchase.
- Building owner tenant improvements including but not limited to: Asbestos removal, paving, concrete, contractor's general conditions, contractor's overhead and profit, electrical, heating, ventilation and air conditioning systems (HVAC), plumbing, flooring, rough and finish carpentry and millwork and associated labor and materials, and utility fees.
- Capital expenditures include donations of equipment or facilities to a facility.
- Capital expenditures do not include routine repairs and maintenance costs that do not add to the utility of useful life of the asset.

Concurrent review means the process by which applications competing to provide services in the same planning area are reviewed simultaneously by the department. The department compares the applications to one another and these rules.

Concurrent Review

The department will review non-emergent PCI applications using the concurrent review cycle described in this section. There are _____ concurrent review cycles each year; a cycle begins in _____.

Applicants must submit applications for review according to the following table:

		Application Submission Period			Department Action	Application Review Period		
Concurrent Review Cycle	Letters of Intent Due	Receipt of Initial Application	End of Screening Period	Applicant Response	Beginning of Review Preparation	Public Comment Period (includes public hearing if requested)	Rebuttal Period	Exparte Period
	First working day through last working day of _____of each year.	First working day through last working day of _____ of each year.	Last working day of _____ of each year.	Last working day of _____ of each year.	_____ **through** _____ **15**	**60-Day** Public comment period Begins ____ 16 of each year or the first working day after _____ 16.	**30-Day** Rebuttal period Applicant and affected party response to public comment.	**45-Day** Exparte period Department evaluation and decision.

Non-emergent Percutaneous coronary interventions (PCI)-Methodology. ????????

This is where a numeric methodology will be described. Please see the sample methodology that may be useful in our discussions.

Standards

Hospital volume requirements

PCI programs in hospitals with and without on-site surgery should have minimum annual PCI volumes of greater than 300 and optimal annual volumes of greater than 400 including 36 primary PCIs.

A minimum of 300 annual PCIs by the end of year two and an optimal annual volume of greater than 400 by year three and each year thereafter.

Operator volume requirements

Operators should have minimum annual PCI volumes of greater than 75 and an optimal annual volume of 100 including a minimum of 11

annual primary PCIs and an optimal volume of 18 primary PCIs.

- Operators in newly established programs should have a lifetime experience of 500 PCIs as primary providers.

- New Operators with less than 75 annual PCIs and less than 500 lifetime experience should be mentored by an experienced operator until it is determined that their skills and outcomes meet national standards.

- New programs and operators should achieve the minimum annual volumes within two years. There are no restrictions on operators meeting their annual volume requirements at more than one hospital.

Credentialing Requirements

The hospital must have a sufficient number of interventional cardiologists on staff so that both primary and elective PCIs can be performed in a timely manner. The hospital must have experienced interventional cardiologists who meet the established minimum lifetime and annual PCI volumes. All operators must be credentialed and privileged to perform elective and primary PCIs. All operators performing PCIs must

meet the following requirements:

- Board certification in internal medicine and cardiovascular disease or Board Certification in interventional cardiology by the American board of internal medicine.

- Lifetime experience of 500 PCIs as primary providers and greater than 75 PCIs annually for the previous two years, or a requirement for mentoring by an experienced operator who performs greater than 150 PCIs per year until proficiency is verified and it is determined that skills and outcomes meet national standards.

The applicant's catheterization laboratory must be staffed by a qualified, trained team of technicians and nurses experienced in interventional labs and in the treatment of acutely ill patients with hemodynamic and electrical instability.

Nursing staff should have coronary care unit experience and have demonstrated competency in invasive hemodynamic monitoring, temporary pacemaker operation, and intraaortic balloon pump management.

Staff should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.

Ancillary Support Services

The applicant hospital must have a signed written agreement with a hospital with on-site cardiac surgery and with cardiac surgeons stating that referred patients will be accepted based on their medical condition.

- The availability of the back-up hospital's surgical team and operating room must be confirmed before the start of elective PCIs.

- The backup hospital and surgeons must agree to provide cardiac surgical backup for emergency CABG twenty four hours per day, seven days per week and during all hours that elective PCIs are being performed at the hospital without on-site surgery.

- All clinical data including images and videos must be transferred with the patient.

- The interventional cardiologist must directly communicate and review with the cardiac surgeon the clinical reasons for urgent transfer and the clinical condition of the patient.

The hospital must provide a mode of emergency transport and/or have a signed transportation agreement with a vendor who will expeditiously transport by air or land all patients who experience complications during elective PCIs that require transfer to a backup hospital with on-site cardiac surgery.

- Transportation shall begin in less than twenty minutes.

- The emergency transport staff must be qualified, trained and ACLS certified and have the skills, experience, and equipment to monitor and treat the patient en route and to manage an intra-aortic balloon pump (IABP).

- The hospital must be able to document that the transportation time from the decision to transfer the patient with an elective PCI complication to arrival in the operating room of the backup hospital is less than 90 minutes and ideally less than 60 minutes.

- No less than two annual timed transportation drills will be performed and reported to the quality program.

Informed consents for elective (and primary) percutaneous coronary interventions must explicitly communicate to the patients that the intervention is being performed without on-site surgery backup and address risks related to transfer, the risk of urgent surgery, and the established emergency transfer agreements.

Quality Assurance

The hospital will conduct regular, ongoing quality assurance/improvement evaluation and analysis of the outcomes (success and complication rates) of elective PCIs, benchmarking, compliance with hospital and program guidelines for patient and lesion selection and exclusion and device utilization, reviews of patients transferred for emergency cardiac surgery, and formalized case reviews.

Surgeons and backup hospitals shall formally participate in the review of all elective PCIs transferred to the backup hospital.

The hospital's cardiac catheterization laboratory and PCI program will fully participate in a national percutaneous

coronary intervention data base such as the American College - National Cardiovascular Data Registry (ACC-NCDR) in the United States.

Requirements for New Applicants

The applicant hospital must provide a detailed demographic and patient need analysis/assessment of its service area that documents an unmet need for the provision of adult elective percutaneous coronary interventions and its plans to address this unmet need, including providing access to those with lack of insurance or in areas with insufficient numbers of cardiologists. The assessment must demonstrate how the implementation of a new elective PCI program in their community would result in improved clinical access and outcomes for the patient population served.

The hospital must submit a detailed analysis of the impact that their new elective PCI program will have on the utilization and volume of PCI performance at other hospitals with established elective PCI programs that are currently providing this service to the same patient population with an opportunity for the other hospitals in the community to respond.

Hospitals applying for new elective PCI programs without on-site

cardiac surgery must apply and qualify for participation in a well-powered, prospective randomized multiple site study, assessing the outcomes of elective PCIs performed in hospitals with and without on-site cardiac surgery as a prerequisite for approval.

Hospitals applying must submit a detailed analysis of the impact the new elective PCI services will have on the Cardiovascular Disease and Interventional Cardiology Fellowship Training programs at the University of Washington with an opportunity for the University to respond.

The hospital must submit a detailed analysis of the projected volume of elective percutaneous coronary interventions that it anticipates will be performed in years one, two and three. All new elective PCI programs are to be in compliance with national guidelines and state of Washington standards for annual institutional volumes for the performance of elective PCIs by the end or year two. The institution must be performing a minimum of 300 annual PCIs by the end of year two and an optimal annual volume of greater than 400 by year three. The projected volumes must be sufficient to assure that all interventional cardiologists working only at this hospital will be able to meet volume standards (minimal greater than 75, optimal greater than 100), for annual elective PCIs by year two. Inability to meet

volume standards may result in a review of certificate of need approval.

New elective PCI programs must submit a plan on how they will be able to effectively recruit and staff the new cardiac catheterization laboratory program with qualified nurses, catheterization laboratory technicians, and interventional cardiologists without negatively effecting existing elective PCI programs in the same service area.

Hospitals applying must have two functional and fully equipped cardiac catheterization laboratories with all appropriate devices, optimal digital imaging systems, life sustaining apparati including IABP, staffed by qualified, experienced nursing and technical staff with documented competencies in the treatment of acutely ill patients.

Applicant hospitals must be prepared and staffed to perform primary emergency PCI 24 hours per day, seven days per week in addition to the scheduled PCIs.

Patient Exclusion Criteria for Hospitals that do not provide on-site Cardiac Surgery---????? Should these be included as a CoN

standard

In order to minimize complications and maximize the procedural success, rigorous patient and lesion criteria must be applied to all patients undergoing elective PCI at a hospital without on-site surgery.

Patients with increased risk for procedural failure and increased potential for clinical demise if peri-procedural complications occur shall have elective PCI performed in a hospital with on-site cardiac surgery.

High risk patient criteria including decompensated congestive heart failure, left ventricular ejection fraction less than twenty five percent, left mail coronary artery stenosis greater than fifty percent, or three vessel disease unprotected by pervious CABG, single target lesion that supplies over fifty percent of viable myocardium, renal failure, recent CVA, coagulation disorders, and other serious, complicated, or uncontrolled medical conditions are to be referred to a hospital with on-site cardiac surgery for the performance of elective PCIs.

Applying the most recent SCAI criteria and definitions of patients and lesion case selection, high risk patients with low

and high risk lesions and low risk patients with high risk lesions are excluded from having elective PCIs performed at a hospital with off-site backup surgery.

Low risk patients with low risk lesions will be eligible to have elective PCI performed at hospitals without on-site cardiac surgery.

After two years of operation, institutions and operators whose risk-adjusted outcome statistics are equivalent or superior to risk adjusted national data registries may apply for expansion of their patient selection criteria to include low risk patients with high risk lesions.

Patients whose angiographic findings indicate that atherectomy devices (directional, rotational, laser) and/or extractional thrombectomy are likely to be used will be excluded from having an elective PCI performed at a hospital without on-site surgery.

Percutaneous Transluminal Angioplasty (PTCA), PTCA with stent implantation, and cutting balloon atherectomy will be allowed in hospitals without on-site surgery.

Ongoing Compliance with Standards

If a certificate of need is issued, it will be conditioned, at a minimum, to require ongoing compliance with the certificate of need standards. Failure to meet the conditioned standards may be grounds for revocation or suspension of a hospital's certificate of need, or other appropriate licensing or certification actions.

Tiebreakers

Data Source

Physical Location

Example should a facility that has on-site inpatient hospital services include a permanent structure that is attached to or contiguous with an inpatient hospital facility????

Sample—Need forecasting methodology

The data used for evaluating applications submitted during the concurrent review cycle will be the most recent three years CHARS data available at the close of the application submittal period for that review cycle.

Step 1. Compute the planning area's current capacity. In those planning areas where a new program has operated less than three years, the assumed volume of that hospital will be the greater of the actual volume or the minimum volume standard or the estimated volume described in the approved application, including any adjustments made by the department in the course of review and approval.

Step 2. Adjust the data for patient origin.

Step 3. Compute the average percent of out-of-state use of each planning area. This is calculated by dividing the number of catheter-based therapeutic interventions occurring within the planning area's hospitals that were performed on residents from out-of-state (or on patients whose reported zip codes are invalid) by the sum of interventions performed on residents of that planning area

and out-of-state residents.

Step 4. Compute each planning area's average age-specific use rates.

Step 5. Multiply the planning area's average age-specific use rates by the area's corresponding forecast year population. The sum of these figures equals the forecasted number of catheter-based therapeutic interventions expected to be performed on the residents of each planning area.

Step 6. For each planning area, increase the number of projected catheter-based therapeutic interventions in accordance with the percent of catheter-based therapeutic interventions projected for out-of-state residents.

Step 7. Calculate the net need for additional adult elective coronary intervention programs by subtracting the current capacity from the results of step 6.

Step 8. The department will not grant a certificate of need for new programs if the net need is less than the minimum volume standard. An exception may be made and a certificate of need granted if (h)(i) and either (ii) or

(iii) of this subsection can be met:

(i) The applying hospital meets all the other certificate of need criteria for an adult elective coronary intervention program (including documented evidence of capability of achieving the minimum volume standard); and

(ii) There is no existing program in the planning area; or

(iii) If there is an existing program in the planning area, eighty percent of the results identified for catheter-based therapeutic interventions received interventional services at hospitals more than seventy-five miles away.